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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,937	05/28/2002	Brent C. Gerberding	S63.2-10447	2387

490 7590 10/31/2006

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

HOUSTON, ELIZABETH

ART UNIT PAPER NUMBER

3731

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/063,937

Applicant(s)

GERBERDING, BRENT C.

Examiner

Elizabeth Houston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-10, 13-18, 22-28, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 and 22-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-10, 13-15, 26-28, 34, 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

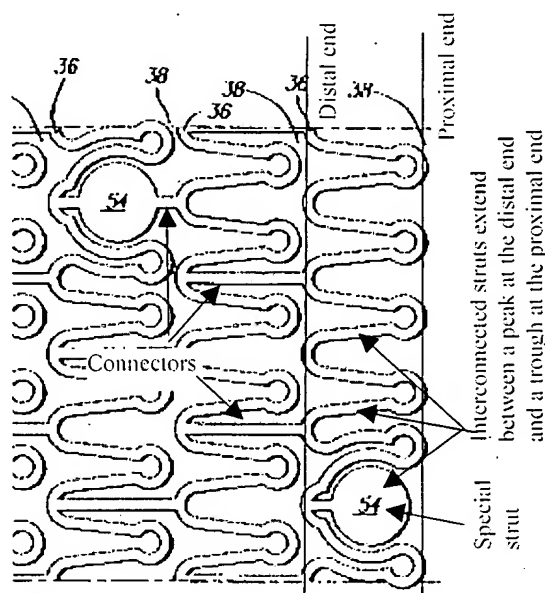
2. **Claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (USPN 6,652,579) in view of Erbel (US 2004/0116998).**

3. **As to claim 1**, in one embodiment, Cox clearly teaches a stent having a longitudinal axis, comprising a first serpentine band and a second serpentine band, formed of interconnected struts (Figs. 6) having a distal end and a proximal end, each strut extending between a peak at the distal end and a trough at the proximal end. At least one of the struts is a special strut (54), each special strut having a first side with a first region of first curvature relative to the longitudinal axis and a second side with a second region of second curvature relative to the longitudinal axis, the first region opposite the second region and having a radiopaque marker (Col. 3, line 14) between the two regions. Each special strut has a plurality of interconnected struts adjacent the first side and a plurality of interconnected struts adjacent the second side, each having curved regions that curve about marker. The first serpentine band is connected to the second serpentine band by a connector (52) or (see below), which extends from one of

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the ends of the first serpentine band to one of the ends of the second serpentine band.

As to claim 26, the special strut extends from (the direction of) the peak to (toward the direction of) the trough.



The special struts are located between the ends of the stent. Some of the special struts (54b or 54c) are located anywhere between the middle of the stent and halfway from the middle to the end of the stent. In other embodiments disclosed by Cox (Figs. 11-15), there is a plurality of radiopaque markers and special struts at the end of the stent.

4. Cox does not disclose a stent with a cover.
5. Erbel discloses an endovascular prosthesis (Fig. 3) or stent (20) comprising at least one cover (25) disposed about at least one section of interconnected serpentine segments, marked at the distal end and proximal end by a plurality of radiopaque markers (35). Erbel teaches that the "use of such radiopaque markers facilitates correct placement" of the stent (Para 90). The nonporous section (25) or cover is disposed about the circumference of the stent, but does not extend about an entire

circumference of the stent and does not cover the entirety of the stent as seen in Fig. 3. The cover extends about the medical device in the region of the special struts. Erbel teaches that the non-porous section "will cause thrombosis or clotting of bodily fluid" (Para 83) as in treating an aneurysm. Erbel further teaches that the partial non-porous or graft covering is beneficial in that it blocks the tear or lesion or aneurysm, while at the same time allows blood to flow from the proximal to the distal end of the vasculature during implantation of the device. (Paras. 70-72).

6. It would have been obvious to one of ordinary skill in the art to incorporate a cover disposed about the stent in the area of radiopaque markers. Using a cover on the stent enhances the properties of the stent to cause thrombosis at the site of the aneurysm or tear while at the same time allowing blood to flow through the stent and the vasculature. Using radiopaque markers at the edge of the cover facilitates correct placement of the cover at the site of the aneurysm or tear in the body lumen. Erbel provides the motivation. The inventions are analogous with each other and with the instant invention therefore a combination is proper.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable Cox in view of Erbel as applied to claim 1 above, and further in view of Barone (USPN 6,613,078).

8. Cox in view of Erbel teach a stent with a cover marked at the periphery by special radiopaque struts as stated above.

9. Cox in view of Erbel do not teach a second cover.

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10. Barone teaches a stent with two covers shown in Fig. 7. The figure shows two stent grafts occluding where the vessel is ruptured but keeping the flow of the blood through the ostium of the vessel branch. Barone states that the use of 2 covers is desirable to repair blood vessels with lesions wherein the wall of the vessel is not in condition to receive and firmly retain an implanted graft (Col 2, lines 20-25 and Col 1, lines 8-17).

11. At the time of the invention it would have been obvious to one of ordinary skill in the art to combine the second cover of Barone into the stent of Wolinky in view of Erbel and the stent of Cox in view of Erbel. Barone provides the motivation in that a stent with two covers enhances the function of the stent since it can be used to repair branched vessels with multiple lesions. The inventions are analogous with each other and the instant invention and so the combination is proper.

12. Claims 13 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Erbel as applied to claim 1 above, and further in view of admitted prior art (admission).

13. Cox in view of Erbel disclose the claimed invention as stated above except for the different forms of radiopaque markings.

14. Admission discloses that the radiopacity may be provided by plating, painting, pressing, swaging or welding or "any other suitable means known in the art" (specification page 8, Para 0045). Additionally, Admission discloses, "One of ordinary skill in the art at the time of the invention would recognize that radiopaque markers in

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the form of plated, coated, painted, swaged or welded radiopaque material have different characteristics." (Remarks, 04/24/06, page 7, Para 4).

15. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the radiopacity by the various forms since it was well known in the art.

Response to Arguments

1. Applicant's arguments with respect to claims 1, 2, 4-10, 13-15, 26-28, 34 and 35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh




ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

10/28/06